

### Remarks

The June 5, 2003 Office Action makes a number of candid statements relating to the prior art:

Kiefer et al. does not have optical or spectrophotometric measurements for either the alcohol or the carbon dioxide . . . .

The combination [Kiefer et al. and Forrester et al.] does not multiplex the optical signals . . . .

Kiefer et al. does not update the threshold based on previous measurements for the patient . . . .

The above combination [Kiefer et al., Forrester et al. and Culver et al.] does not update the threshold based on prior measurements for the patent.

Claims 1, 4-6, 8-11, 13-14 and 17-19, as now amended (claims 2-3, 7, 12 and 15-16 have been cancelled), require (1) spectroscopic measurement, and (2) an update of the threshold based on previous measurements for the patient. Further, claims 20-22, 24-26, 29-34, 36-37 and 39-42, as amended (claims 23, 27-28, 35 and 28 have been cancelled), in addition to the two limitations noted above, also include the multiplex limitation.

The cited prior art will now be discussed:

#### Culver et al.

Culver et al. (5,445,160) is not directed to the same problem as Kiefer, or Forrester, that seek to measure breath alcohol. Rather, Culver et al. is directed to a device to measure whether or not a patient is breathing through an endotracheal tube (col. 3, lines 55-62):

A “blip bar” display 32 of eight LEDs will light up with each breath, with the number of LEDs lighting up indicating the amount of CO<sub>2</sub> in the exhalation. A red light 34 will be illuminated if no breath is detected, and at the same time an audible alarm will be sounded

through a speaker (not shown) to indicate that the patient has stopped breathing or that the tube has become dislodged.

The device of Culver et al., is used to detect a single gas in patient breath, and the only gas specifically referenced is CO<sub>2</sub>. Nor does Culver et al. deal with determining the presence of alveolar breath; indeed the term “alveolar breath” is not used in the disclosure of the Culver et al. patent. Culver et al. discloses a rather complicated analysis of the waveform amplitude values of the patient’s four most recent prior breaths, used to calculate a logarithmic amplitude indicative of a patient breath (col. 5, line 66-col. 6, line 14):

The monitor maintains a history in a memory buffer of the four most recent waveform amplitude values, where waveform amplitude is defined as one-half the difference between the peak waveform value  $\text{Slog}(V)_{\text{MAX}}$  (corresponding to an inspiration, i.e., negligible carbon dioxide concentration) and the trough waveform voltage value  $\text{slog}(v)_{\text{MIN}}$  (corresponding to an exhalation). The initial value  $\text{AMP}_{\text{INIT}}$  of each of the four stored waveform amplitudes is an arbitrary value greater than the system’s characteristic noise.

The monitor computes a threshold value  $T$  by averaging the four most recent waveform amplitudes. The next  $\text{slog}(v)_{\text{MAX}}$  must exceed  $T$ , and the following  $\text{Slog}(v)_{\text{MIN}}$  must drop below  $T$ , in order for that section of the  $\text{slog}(v)$  signal waveform to be “detected” as a likely breath.

Culver et al. does not disclose determining threshold concentration of a gas such as CO<sub>2</sub> from a patient’s prior breath indicative of alveolar breath, or for the triggering of the concentration measurement of a second gas component.

#### **Kiefer et al. and Forrester et al.**

As pointed out earlier, the Examiner is in agreement that early reference lacks a teaching of “optical or spectrophotometric measurement,” “does not multiplex the optical signals” and “does not

update the threshold based on previous measurements for the patient.” These features are present in the claims, as amended.

*In re Dembiczak*, 175 F.3d 544, 1560, 50 U.S.P.Q. 2d 1617 (Fed. Cir. 1999) involved an appeal of the rejection under § 103 of claims directed to plastic trash bags with a pumpkin face. The § 103 obviousness rejection was based on a combination of children’s art references (Holiday and Shapiro) and conventional trash bag references. In reversing, the Federal Circuit noted that the portion of § 103 heading “at the time the invention was made” guards against entry into the “tempting but forbidden zone of hindsight”. *Id.* at 998 (citations omitted). Specifically, the Federal Circuit noted that:

The Board’s decision is limited to a discussion of the ways that the multiple prior art references can be combined to read on the claimed invention. . . . This reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the Holiday and Shapiro references teach or suggest their combination with convention trash or lawn bags to yield the claimed invention. *Id.* at 1000.

And see, *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354, 60 U.S.P.Q. 2d 1001 (Fed. Cir. 2001) holding that:

[I]f references taken in combination would produce a “seemingly inoperative device”, we have held that such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness. (Citations omitted).

Here, it is submitted that there is no suggestion to combine Culver et al. with any of the other cited references because Culver et al. is directed to an entirely different issue (patient breathing). Moreover, even if combined, the complicated logarithmic amplitude calculation of Culver et al. does not produce “triggering at least one concentration spectroscopic measurement of a second component of the breath once alveolar breath is in the analysis chamber based on the concentration

of the first component in a previously expired breath” as claimed by applicant in the amended claims here presented.

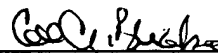
Allowance of claims 1, 4-6, 8-11, 13-14, 17-22, 24-26, 29-34, 36-37, and 39-42, as amended, is earnestly solicited.

Respectfully submitted

**JONES DAY**

Date: July 15, 2003

By



Coe A. Bloomberg  
Reg. No. 26,605  
Attorney for Applicant

555 West Fifth Street, Suite 4600  
Los Angeles, CA 90013-1025  
(213) 489-3939